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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,300	07/05/2001	Achim Berthold	R00282US (#90568)	8251

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,300

Applicant(s)

BERTHOLD, ACHIM

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 17, 19-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 17, 19-23, and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Application

Receipt of Amendments to the claims and specification filed received on February 6, 2004 is acknowledged. Claims **15, 17, 19-23, and 25** are pending in this application. Claims 1-14, 16, 18, and 24 stand cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 15, 17, 19-23, and 25 under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al (5,151,271) by itself or in view of Ercillo et al (6,416,858) is maintained.

Otsuka et al teaches a pressure sensitive adhering composite medicinal preparation. The composite comprises at least two layers, namely at least one macromolecular layer and polymer layer. The polymer layer contains a polymer or

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copolymer that has a glass transition temperature (T_g) of not lower than -50 degrees Celsius, preferably -45 to 75. This allows an increased degree of diffusion therein of the drug and adjuvant but also does not deteriorate the physical strength. See column 2.

The macromolecular layer functions to secure the preparation to the skin, be compatible with the drug and adjuvant, and allow release of the drug and adjuvant. This layer has a T_g of -70 to -10 degrees Celsius. This temperature allows increased shape holding property, does not cause skin irritation, and does not leave a residue when peeled off. See column 3, lines 1-25. Otsuka teaches a release liner. See examples.

Although Otsuka suggest more than three polymer layers, the reference does not exemplify the third layer or a protective layer.

Ercillo et al teach a multi-layer pressure sensitive adhesive construction. The multi-layer construction contains a facestock (protective layer), a first adhesive layer that has one T_g, the second adhesive layer has a T_g of 10 to 50 degrees lower than the first layer, and a release liner. See Figure 2. Ercillo teaches that the degree of tack possessed by a particular adhesive layer is largely dependent on the glass temperature of the layer. If the T_g is too high the composition fails to act as an adhesive. If the T_g is too low than the adhesive composition will flow too readily, which diminishes converting performance. Ercillo teaches several different embodiments switching the layers with the high T_g and the low T_g to balance improved converting and adherent properties of the composite. See column 3, line 49 to column 4, lines 7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Otsuka and incorporate a third layer. One

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would be motivated to do so since Otsuka teaches that the composite should contain at least two layers; therefore suggesting the incorporation of more than one polymer layer or macromolecular layer respectively.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Otsuka and Ercillo and manipulate the arrangement of the polymer layers according to the glass temperature of the polymer. One would be motivated to do so since Ercillo teaches the manipulation of the adhesive layers based on the glass temperate yields the desired converting performance and adherence properties.

Response to Arguments

Applicant argues that Otsuka teaches does not unambiguously teach that the two polymer layers should have different glass temperatures (T_g) since the glass temperatures have overlapping ranges. Thus, applicant argues that the two layers in Otsuka can have the same T_g whereas instant invention requires different T_g temperatures. Therefore, it is argued that a motivation to modify the system as seen in instant invention is not present. Secondly, applicant argues that Otsuka has a different goal of preventing drug crystallization whereas instant invention addresses the problem of cold-flow phenomenon, i.e. the cohesion of the system. Applicant argues that Ercillo does not pertain to the medical field since it does not contain an active agent and thus one would not look to non-analogous art.

Applicant's arguments have been fully considered but they are not persuasive. Applicant claims a therapeutic system, a method of treating using the system, and a

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process of making the system. The system contains three layer Tg1, Tg2, and Tg3. Tg1 and Tg2 have different temperatures wherein Tg2 has a higher glass transition temperature. Tg1 and Tg3 may have the same or different temperature.

The prior art, Otsuka teaches *at least* two layers, at least one macromolecular layer and at least one polymer layer. Note column 2, lines 1-15. The first polymer layer has a Tg of not lower than -50 Celsius and preferably -40 to $+75$ or -40 to $+45$ Celsius. The second layer has a Tg of -70 to -10 Celsius and preferably -55 to -10 Celsius. It is implicit that these layers have different temperatures since the polymer layer's temperature range is higher than the macromolecular temperature range. Although, it is noted that there is a small overlapping range, the examples effectively demonstrates Otsuka's implicit teaching of two different temperatures. All the examples provide for the polymer layer having a higher temperature than the macromolecular layer. Therefore, applicant's limitation that one layer has a higher temperature than the other is met. Secondly, Otsuka teaches the utilization of more than two layers. The claims recite that the temperature of the third layer may be the same or different than Tg1, thus opening this layer to having any temperature and not denoting any criticality to this layer in regards to temperature. Thus, an additional layer may be applied to the system as suggested by Otsuka and applicant's third layer requirement is met under obviousness. Also, Otsuka teaches that the preparation provides a greater amount of drug since the respective layers contain the drug compared to one layer containing the drug, which further provides motivation to utilize more than two layers if one desired a system that contained a high amount of drug. Thus, it is the examiner's position that the prior art

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reads on the instant claims since the criticality of the invention lies in the two layers having different Tg temperatures with a third layer having any temperature and the prior art teaches two layers with different temperatures and the suggestion of more than two layers.

In regards to the applicant's goal and prior art's goal, the examiner points out that the use of a patent as a reference is not limited to what inventive goal or problem is, it is literature of art for all it contains. Therefore, even though applicant is considered with "cold-flow" and Otsuka has a different "goal", Otsuka teaches applicant's recited system, use of the system, and method of making the system. Furthermore, the examiner points out that the claims are not drawn to the method of "reducing cold-flow" rather they are drawn to a method of use, the system, and the process of making the system. Therefore, applicant's argument that the reference does not teach a method of reducing cold flow is moot.

In response to applicant's argument that Ercillo et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Ercillo et al is in the same field of endeavor as the primary reference and the applicant's. Ercillo et al teach a pressure sensitive adhesive construction containing polymer layers with different Tg. Otsuka teaches a pressure-sensitive adhering composition with different Tg. Applicant teaches a device with polymer layers with

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different Tg. Secondly, Ercillo teaches the adhesive to have improved convertibility (flowing properties) and good adhesion by manipulating the Tg. Otsuka teaches manipulating the Tg of the layers to provide for secure adhesion and improved diffusion of the drug. The applicant, as stated in the arguments, is concerned with cold flow in transdermal systems. Thirdly, Ercillo teaches a general pressure adhesive composition and the same pressure adhesive polymers utilized by Ercillo are the same ones conventionally utilized in the transdermal art to provide for adhesion to the skin.

Lastly, it should be noted that Ercillo is relied upon for its specific teaching of manipulating the Tg of an adhesive construct to improve convertibility and adhesion to the substrate and to demonstrate the state of the art wherein more than two polymer layers are utilized in adhesive constructs. Thus, Ercillo does not have to teach a drug since the primary reference is not lacking in this teaching.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

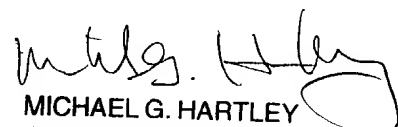
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with alternative Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

April 22, 2004


MICHAEL G. HARTLEY
PRIMARY EXAMINER